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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,868	09/30/2003	Michael Slivka	DEP-5170	7650

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EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,868	SLIVKA ET AL.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-12 and 14-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-12 and 14-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response of 6 October 2006 has been received and placed into the application file. Claims 1, 14 and 21 have been amended; claims 2, 3 and 13 have been cancelled; no new claims have been added; claims 1, 4-12 and 14-41 remain pending in the current application, all of which have been considered on the merits

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-12 and 14-41 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' amended claim 1 (representative generic claim) is directed to a method of treating spinal disc defects comprising preparing a disc treatment site; providing a substantially two-dimensionally shaped disc defect repair material in the form of a strip; and inserting the repair material into the disc to be repaired.

The claims were rejected on the grounds that the disclosure of the instant specification is too limited to be considered enabling for treatment of *any* spinal disc defect with the generically claimed materials, particularly wherein the claimed repair materials encompass any and all bioabsorbable materials. The new limitation in claim 1, requiring the material to be in the form of a strip does not define or limit the material, per se, but rather only defines its shape, which doesn't sufficiently narrow the scope of materials which could be included in this almost limitless

genus. Applicant would appear to allege that *any* spinal disc defect can be *effectively* repaired simply by plugging the defect with any bioabsorbable material which can be provided in an appropriate shape. This has not been enabled by the specification and such an allegation would have to be considered incredible to one of skill in the art. To be able to practice the claimed invention at the claimed scope would require undue experimentation to determine what materials would actually work to effectively treat a spinal disc disorder.

The breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work that not without actually making and testing them then the instant application does not support the breadth of the claims. In the instant case it is highly improbable that many, if any, of the materials encompassed by the broad genus will more likely than not be useful in the manner disclosed, nor does the instant specification provide the guidance needed to select which materials would work in the claimed method.

The claims are essentially of limitless breadth. It is implied that so long as the specification provides one with the ability to test any particular embodiment which is encompassed by the material limitations of a claim, one can thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don't. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This 'make and test' position is inconsistent with

the decisions in *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), *Amgen v. Chugai Pharmaceuticals Co. Ltd.*, 13 USPQ2d, 1737 (1990), and *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988). *In re Wands* stated that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims.

Breadth alone is not the issue, however. *In re Fisher,* 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that *scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art*; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (emphasis added). In the instant case, for the reasons set forth above, the broad scope of the instant claims do not bear a reasonable correlation to the scope of enablement provided by the specification; and thus the claims are not deemed enabled for their full scope.

In response, Applicants have argued that selection of repair materials which could successfully be used in the instantly claimed method would have been well within the purview of one of ordinary skill in the art. In support, Applicants refer to the teachings of Gan et al, who disclose several varieties of polymeric materials which may be used in the repair of vertebral disc defect, as evidence that a variety of suitable materials useful for the repair of vertebral discs were known in the art, and thus selection of appropriate materials within the scope of the claims would not require undue experimentation.

These arguments are not found persuasive. It is respectfully submitted that Applicants' reference to the Gan et al reference fails to show that at the time the invention was made Applicants had enabled one of ordinary skill in the art to successfully carry out the claimed method, commensurate in scope with the breadth of the claims. The fact that Gan et al disclose numerous species of polymeric materials is actually considered to support the Examiner's position, the genus claimed by Gan et al (biocompatible polymeric materials) is much narrower than that currently claimed by Applicants (*any and all* materials that can be provided in a strip form), yet Gan et al disclose numerous examples of suitable polymer materials. The level of description, guidance and teachings provided by Gan et al is representative of what is necessary to fully enable for a broad genus of materials, particularly in an unpredictable art; in contrast, the instant claims are much broader than those of Gan et al, yet lack any description, guidance or teachings on suitable materials, much less a representative number of species of materials which are representative of the full scope of the claims. Relying on the teachings of Gan et al only enables one for the materials disclosed by Gan et al; for enablement for the full scope of the current claims, additional description of specific materials which can be used, or at the least, teachings or guidance on how to select appropriate materials, is necessary, yet is lacking.

Additionally, it is reiterated that the field of Applicant's invention has been deemed unpredictable. It is noted that the greater the degree of unpredictability and/or complexity of the

state of the art with regard to particular disease states or conditions, the more comprehensive and substantial the teachings and disclosure must be to support such an invention since such an invention would be claiming an outcome that would not have been reasonably expected by the skilled artisan. It is acknowledged that Applicant is not required to enable each and every single embodiment encompassed by the claims, but must enable a sufficient number to be reasonably representative of that which is claimed. In this regard, Applicant's statement that the scope of enablement must only bear a "reasonable correlation" to the scope of the claims is not disputed.

However, due to the fact that Applicant has not provided any evidence or persuasive argument in the present disclosure or in the response to the rejection made under 35 U.S.C. 112, first paragraph, as to how one of ordinary skill in the art would make and/or use the presently claimed invention, in its full scope, without an undue level of experimentation. Applicant is reminded that the key word in the phrase "undue experimentation" is the word "undue", not the work "experimentation". Experimentation, in and of itself, does necessarily prompt a finding of a lack of enablement. Rather, should the skilled artisan need to practice an undue amount of experimentation in order to determine how to make and/or use the presently claimed invention, then a finding of a lack of enablement is proper. In consideration of the fact that the specification fails to provide sufficient direction or guidance to such effect, and, further, in light of the fact that the state of the art with regard to the treatment of such conditions is highly complex and poorly understood, it remains that the specification is viewed as lacking an enabling disclosure of the presently claimed subject matter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leon B Lankford, Jr
Primary Examiner
Art Unit 1651